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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,263	09/28/2006	Jeffrey W. Ruberti	20780-0016	3481

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EXAMINER	
BECCIA, CHRISTOPHER J	

ART UNIT	PAPER NUMBER
3775	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,263	RUBERTI ET AL.	
	Examiner	Art Unit	
	CHRISTOPHER BECCIA	3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *164-182* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *164-182* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 January 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/9/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

The abstract of the disclosure is objected to because it is not within the range of 50 to 150 words. Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within **the range of 50 to 150 words**. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Drawings

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the current drawings are blurry, indistinct, and difficult to discern. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 164-169, 172-175, 178, and 180** are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,268,405 to *Yao et al.*

As to **Claim 164,** *Yao* discloses a physically cross-linked gel (Col. 6, Lines 28-39) produced by the method of comprising: dissolving a biocompatible vinyl polymer in a first solvent to form a vinyl polymer solution (Col. 6, Lines 40-52); introducing the vinyl polymer solution in a volume of a second solvent to cause gelation, the second solvent having a higher Flory interaction parameter at a process temperature than the vinyl polymer solution to form a biocompatible cross- inked gel, and wherein the cross-linked gel is suitable for in vivo use (Col. 6, Lines 40-68, and Col. 8, Lines 4-19).

As to **Claim 165,** *Yao* discloses a physically cross-linked gel wherein the vinyl polymer is polyvinyl alcohol having a molecular weight of about 50 kg/mol to about 300 kg/mol (Col. 6, Lines 53-63).

As to **Claim 166,** *Yao* discloses a physically cross-linked gel wherein the vinyl polymer solution is an aqueous solution of about 10 weight percent to about 30 weight percent polyvinyl alcohols based on the weight of the solution (Col. 7, Lines 4-9).

As to **Claim 167,** *Yao* discloses a physically cross-linked gel wherein the vinyl polymer solution is introduced in an aqueous solution of sodium chloride from about 1.5 molar to about 6.0 molar (Col. 7, Lines 9-20, and Col. 7, Lines 59-65).

As to **Claim 168,** *Yao* discloses a physically cross-linked gel wherein the vinyl polymer solution is introduced in an aqueous solution of sodium chloride from about 1.5 molar to about 3.0 molar (Col. 7, Lines 9-20, and Col. 7, Lines 59-65).

As to **Claim 169,** *Yao* discloses a physically cross-linked gel wherein the vinyl polymer solution is introduced in an aqueous solution of sodium chloride from about 1.75 molar to about 6.0 molar (Col. 7, Lines 9-20, and Col. 7, Lines 59-65).

As to **Claim 172,** *Yao* discloses a physically cross-linked gel substantially free of chemical crosslinkers (Col. 5, Lines 50-60).

As to **Claim 173,** *Yao* discloses a physically cross-linked gel comprising at least about 10 weight percent polyvinyl alcohol solution gelled by immersion in about 2 to about 3 molar sodium chloride wherein the hydrogel is about 14 percent to about 21 percent physically crosslinked (Col. 7, Lines 4-58, and Col. 10, Lines 5-38).

As to **Claim 174,** *Yao* discloses a physically cross-linked gel wherein the gel comprises about 12 to about 29 percent polyvinyl alcohol (Col. 7, Lines 4-9).

As to **Claim 175,** *Yao* discloses a physically cross-linked gel wherein the vinyl polymer solution contains one or more non-gelling components (Col. 8, Lines 4-20).

As to **Claim 178,** *Yao* discloses an article of manufacture comprising a vinyl polymer gel having at least one gradient of mechanical properties (Col. 12, Lines 21-30).

As to **Claim 180,** *Yao* discloses a physically cross-linked gel further comprising a therapeutic agent (Col. 10, Lines 46-54).

3. **Claim 179** is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,047,055 to *Bao et al.*

As to **Claim 179,** *Bao* discloses a one-piece prosthetic intervertebral disk comprising a polyvinyl polymer hydrogel wherein the distribution of mechanical properties of the one-piece prosthetic intervertebral disk approximates the spatial distribution of the mechanical properties of the combination of the nucleus pulposis and the annulus fibrosis of the natural intervertebral disk (Col. 6, Lines 20-69).

The examiner notes that the claims are written including product-by-process limitations which are being treated as product-by-process limitations for examination purposes. It is further noted by the examiner that the devices of Yao et al. and Bao et al. appear to be substantially identical to the devices claimed; therefore the burden is upon the applicant to come forward with evidence establishing an unobvious difference between the products based on any varying steps between the processes. In re Marosi, 218 USPQ 289 (Fed. Cir. 1983).It appears that the claims are intended to be directed to a method of manufacture, as the body of the claims and Applicant's disclosure contain many steps directed to the actual manufacture of the product. In order to expedite prosecution, the examiner has also supplied references directed to the process by which the devices are manufacture.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. **Claims 170, 171, 176, and 177** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,268,405 to *Yao et al. i*n view of U.S. Patent No. 5,091,121 to *Nakada et al.*

As to **Claims 170, 171, 176, and 177,** *Yao* discloses the claimed invention using a material to fill an implant for use in the body (Col. 8, Lines 4-20) except for wherein the physically cross-linked gel further comprising hyaluronic acid or polyacrylic acid.

Nakada et al. discloses a physically cross-linked gel further comprising hyaluronic acid or polyacrylic acid (Col. 5, Lines 43-53) in order to achieve the predictable result of filling an implant for use in the body (Col. 4, Lines 32-57).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the hydrogel of *Yao* with the hyaluronic acid or polyacrylic acid of *Nakada* in order to achieve the predictable result of filling an implant for use in the body.

6. **Claims 181 and 182** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,047,055 to *Bao et al.* in view of U.S. Patent No. 6,268,405 to *Yao et al.*

As to **Claims 181 and 182,** *Bao* discloses the claimed invention except for wherein the biocompatible vinyl polymer hydrogel is formed by a method comprising the steps of: providing a vinyl polymer solution comprising a vinyl polymer dissolved in a

first solvent; mixing the vinyl polymer solution with a gellant, wherein the resulting mixture has a higher Flory interaction parameter than the vinyl polymer solution; inducing gelation of the mixture of vinyl polymer solution and gellant; controlling the gelation rate to form a viscoelastic solution; and wherein the property of the gel is controlled by controlling the rate of the introduction of the vinyl polymer solution to the second solvent, the second solvent having a higher Flory interaction parameter at a process temperature then the vinyl polymer solution to form a biocompatible gel.

Yao et al. discloses a hydrogel wherein the biocompatible vinyl polymer hydrogel gel (Col. 6, Lines 28-39) is formed by a method comprising the steps of: providing a vinyl polymer solution comprising a vinyl polymer dissolved in a first solvent (Col. 6, Lines 40-52); mixing the vinyl polymer solution with a gellant, wherein the resulting mixture has a higher Flory interaction parameter than the vinyl polymer solution; inducing gelation of the mixture of vinyl polymer solution and gallant (Col. 6, Lines 40-68, and Col. 8, Lines 4-19); controlling the gelation rate to form a viscoelastic solution; and wherein the property of the gel is controlled by controlling the rate of the introduction of the vinyl polymer solution to the second solvent, the second solvent having a higher Flory interaction parameter at a process temperature then the vinyl polymer solution to form a biocompatible gel (Col. 6, Lines 40-68) in order to form a hydrogel suited to mimic the properties of the nucleus pulposis (Col. 9, Lines 23-31.)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the hydrogel intervertebral disc nucleus of *Bao* with the

hydrogel of *Yao* to form a hydrogel suited to mimic the properties of the nucleus pulposis.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER BECCIA whose telephone number is (571)270-7391. The examiner can normally be reached on M-F 7:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Melba Bumgarner can be reached on 571-272-4709. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTOPHER BECCIA/
Examiner, Art Unit 3775
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733